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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/820,677	04/08/2004	Lisa Lynn Shafer	P-10966.00 US	8518

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MEDTRONIC, INC.
710 MEDTRONIC PARK
MINNEAPOLIS, MN 55432-9924

EXAMINER

GEDEON, BRIAN T

ART UNIT	PAPER NUMBER
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3766

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	01/31/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary

Application No.

10/820,677

Applicant(s)

SHAFER, LISA LYNN

Examiner

Brian T. Gedeon

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 13 November 2006.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-4,8-10,15,17-42,57-70 and 130-197 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-4,8-10,15,17-42,57-70 and 130-197 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 08 April 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>4/21/05</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Objections

1. Claim 34 is objected to because of the following informalities: claim 34 is improperly dependent upon itself. Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

2. Claims 68-70 recite the limitation "proinflammatory cytokine" in reference to claim 54. There is insufficient antecedent basis for this limitation in the claim.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

3. Claims 1, 2, 4, 8-10, 15, and 131-133 are rejected under 35 U.S.C. 102(e) as being anticipated by Kees et al. (Journal of Immunology 145, 2003 pp 77-85).

In regard to claims 1, 2, 4, 8-10, 15, Kees et al. provide teaching that stimulation of the sympathetic nervous system, in particular the splenic nerve, inhibits or

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"attenuates" secretion of tumor necrosis factor (TNF) and Interluken-6 (IL-6), both which are pro-inflammatory mediators secreted to stimulate an immune response to trauma, page 82 column 2 lines 3-5, 30-35, 37-39, and 46-48. The methods of Kees et al. stimulate the splenic nerve by electrical pulses from two platinum electrodes, page 79 columns 1 and 2 section 2.3.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. Claims 3, 17-19, 54-70, 130, and 134-197, are rejected under 35 U.S.C. 103(a) as being unpatentable over Kees et al. (Journal of Immunology 145, 2003 pp 77-85) in view of Rezai (US Patent no. 6,885,888).

In regard to claims 3 and 56, Kees et al. substantially describe the invention as claimed except do not explicitly teach that the electrical stimulation pulses are generated from an implantable pulse generator. Rezai discloses a method for electrical stimulation of the sympathetic nerve chain, and teaches the implantable electrodes for stimulation must be connected to a power source that includes a pulse generator, column 8 lines 10-12. Therefore it would have been obvious to one of ordinary skill in the art at the time the invention was made to connect the electrodes to a pulse

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generator since it is well known the electrical stimulation art that supply electrical stimuli from an implantable pulse generator.

In regard to claim 17, 54, and 139-197, Kees et al. substantially provides the teaching that stimulation of the sympathetic nervous system, in particular the splenic nerve, inhibits or "attenuates" secretion of tumor necrosis factor (TNF) and Interluken-6 (IL-6), both which are pro-inflammatory mediators secreted to stimulate an immune response to trauma, page 82 column 2 lines 3-5, 30-35, 37-39, and 46-48. The methods of Kees et al. stimulate the splenic nerve by electrical pulses from two platinum electrodes, page 79 columns 1 and 2 section 2.3. Rezai in a similar field of endeavor, teaches that stimulation of the sympathetic nervous system is effective in treating certain physiological disorders such as, but not limited to, hyperhydrosis, complex regional pain, abnormal cardiac out, cardiac contractility, excessive blushing, hypertension, renal disease, heart failure, liver disorders, pancrease disorders, etc, col 2 lines 26-42. Rezai also teaches that the number of disorders to be treated is limited only by the number, variety, and placement of electrodes along the sympathetic nervous system, col 2 lines 39-42. Due to the lack of criticality in the Applicant's disclosure regarding treatment for a specific disease, it is assumed that in view of the teachings of Kees, the sympathetic nervous sytem stimulation of Rezai is sufficient to induce an attenuation of an immune response and can efficiently treat physiological and pathological disorders mediated by an immune response.

In regard to claims 18 and 19, Kees in view of Rezai teach that sympatheic nervous system stimulation is effective for attenuating an immune response and for

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treating physiological and pathological disorders. The system of Rezai also includes a sensor that generates a signal related to the activity resulting from a physiological disorder, wherein said signal can be used to regulate the stimulation to treat the physiological disorder, col 17 lines 6-9.

In regard to claims 55, 57-67, 130 and 134-138, Kees et al. substantially describe the invention as claimed except do not explicitly teach where the electrical stimulation pulses are applied, particularly the splenic nerve, page 79 columns 1 and 2 section 2.3. Rezai teaches that sympathetic nervous system stimulation can be applied along the sympathetic nerve chain consisting of any of the cervical ganglion or ganglia, thoracic ganglion or ganglia, lumbar ganglion or ganglia, sacral ganglia, or any combination thereof associated with a particular physiological disorder to be affected, modulated, treated, alleviated, or ameliorated, col 1 lines 50-62; the components of the sympathetic nerve chain are depicted in figure 1 of Rezai. In view of Rezai's teaching, it would have been obvious to one of ordinary skill in the art at the time the invention was made to apply stimulation pulses at a particular site, such as those claimed, since all that is required is that the electrodes be exposed or in contact with the desired ganglia of the sympathetic nerve chain, col 6 lines 65-67 and col 7 lines 66-67 through col 8 lines 1-9.

In regard to claims 68-70, Kees teaches that sympathetic nervous system stimulation, particularly near the splenic nerve, is effective in attenuating an immune response by inhibiting the release of proinflammatory mediators such as TNF and IL-6, page 82 column 2 lines 3-5, 30-35, 37-39, and 46-48.

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5. Claims 20-42 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kees et al. (Journal of Immunology 145, 2003 pp 77-85) in view of Rezai (US Patent no. 6,885,888) in view of Tracey (US Patent no. 6,610,713).

In regard to claims 20-42, Kees in view of Rezai substantially describe the invention as claimed, including the use of a sensor that measures a characteristic of a physiological or pathological disorder so that the therapy being delivered can be adjusted to better treat the disorder, col 17 lines 6-9. However, neither Kees nor Rezai describe the characteristic used by the sensor to adjust the therapy, but the sensed characteristic is assumed to be indicative of the disease or disorder. Tracy discloses a method of stimulating a vagus nerve is effective in treating in attenuating proinflammatory disorders, col 6 lines 31-43, by modulating cells that output proinflammatory cytokines, col 6 lines 44-67 through col 7 lines 1-14, and particularly teaches that characteristics of an inflammatory or immune response to be in the form of cytokine or other mediators. Therefore it would be obvious to one of ordinary skill in the art at the time the invention was made in view of Tracey, that in order to effectively attenuate an immune response feedback regarding the characteristics of the response be measured so as to optimally adjust therapy.

Conclusion


6. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brian T. Gedeon whose telephone number is (571) 272 3447. The examiner can normally be reached on M-F 8:30-5:00.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert E. Pezzuto can be reached on (571) 272 6996. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Brian T. Gedeon
Patent Examiner
Art Unit 3766


Robert E. Pezzuto
Supervisory Patent Examiner
Art Unit 3766

BTG